

FASENRA®

30mg Solution for Injection in Pre-filled Pen

What is in this leaflet

1. What FASENRA is used for
2. How FASENRA works
3. Before you use FASENRA
4. How to use FASENRA
5. While you are using it
6. Side effects
7. Storage & Disposal of FASENRA
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP Revision
11. Serial Number

What FASENRA is used forAsthma

FASENRA is used to treat severe eosinophilic asthma in adults from 18 years. Eosinophilic asthma is a type of asthma where patients have too many eosinophils in the blood or lungs.

FASENRA is used together with other medicines to treat asthma (inhaled corticosteroids plus other asthma medicines).

Eosinophilic granulomatosis with polyangiitis (EGPA)

FASENRA is used to treat EGPA in adults. EGPA is a condition where people have too many eosinophils in the blood and tissues and also have a form of vasculitis. This means there is inflammation of the blood vessels. This condition most commonly affects the lungs and sinuses but often affects other organs such as the skin, heart and kidneys.

FASENRA can reduce symptoms and prevent flare-ups of EGPA. This medicine may also allow you to reduce the daily dose of oral corticosteroids you need to control your symptoms.

How FASENRA works

Eosinophils are white blood cells involved in asthma and EGPA inflammation. By attaching to the eosinophils, FASENRA helps to reduce their numbers and inflammation.

Before you use FASENRA- When you must not use it

Do not use FASENRA

- If you are allergic to benralizumab or any of the other ingredients of this medicine (listed in ingredients). Check with your doctor, nurse or pharmacist if you think this applies to you.

- Before you start to use it

Before you use FASENRA, tell your doctor, nurse or pharmacist:

- If you have had any symptoms of an allergic reaction (see section 'side effects'). Allergic reactions have occurred in patients receiving this medicine.
- If you have a parasitic infection or if you live in an area where parasitic infections are common or if you are travelling to such region, as this medicine may weaken your ability to fight certain types of parasitic infections.

- Taking other medicines

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Do not suddenly stop taking or change the dose of your other medicines for your condition once you have started FASENRA.

These medicines (especially ones called corticosteroids) must be stopped gradually, under the direct supervision of your doctor and on your response to FASENRA.

How to use FASENRA- How much to use & when to use it

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Asthma

The recommended dose is 30 mg every 4 weeks for the first 3 injections, and then every 8 weeks thereafter.

EGPA

The recommended dose is an injection of 30 mg every 4 weeks.

FASENRA Pen is for single-use only.

FASENRA is given as an injection just under the skin (subcutaneously).

You and your doctor or nurse should decide if you should inject FASENRA yourself.

You or your caregiver should receive training on the right way to prepare and inject FASENRA. Read the 'Instructions for Use' carefully before using FASENRA. See 'Instructions for use of FASENRA pre-filled pen'.

- How long to use it

Do not stop receiving injections of FASENRA unless your doctor advises you to. Interrupting or stopping the treatment with FASENRA may cause your asthma symptoms and attacks to come back.

If your asthma symptoms get worse while receiving injections of FASENRA, call your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

- If you forget to use it

If you have forgotten to inject a dose of FASENRA, talk to your doctor, pharmacist or nurse as soon as possible.

- If you use too much (overdose)

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not exceed your prescribed dose without seeking medical advice.

While you are using FASENRA- Things you must do

Use FASENRA as directed by your doctor.

- Things you must not do

Do not stop using FASENRA unless advised by your doctor.

- Things to be careful of

Children and adolescents

The safety and benefits of this medicine are not known in children below the age of 18.

Pregnancy and breast-feeding

If you are pregnant, if you think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

It is preferable to avoid the use of FASENRA during pregnancy. It is unknown if FASENRA may harm your unborn baby.

It is not known whether the ingredients of FASENRA can pass into breast milk. If you are breast-feeding or plan to breast-feed, you must check with your doctor before you use FASENRA.

Driving and using machines

FASENRA has no or negligible effect on your ability to drive or to use tools or machines.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions

Some people may have allergic reactions. These reactions may occur hours or days after the injection.

Symptoms can include:

Common (These may affect up to 1 in 10 people):

- Hives
- Rash

Unknown (the frequency cannot be determined from the available data):

- Swelling of your face, tongue, or mouth
- Breathing problems
- Fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)

Seek medical attention immediately if you think you may be having a reaction. If you may

have had a similar reaction to any injection or medicine, tell your doctor before you are given FASENRA.

Other side effects:

Common (These may affect up to 1 in 10 people)

- Headache
- Pharyngitis (sore throat)
- Fever (high temperature)
- Injection site reaction (e.g. pain, redness, itching, swelling near where the injection was given)

If you notice any side effects not mentioned in this leaflet, please inform your doctor/dentist or pharmacist.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage & Disposal of FASENRA

- Storage

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Store in the original package to protect from light.
- Store in a refrigerator (2°C to 8°C).
- FASENRA may be kept at room temperature up to 30°C for a maximum of 14 days. After removal from the refrigerator, FASENRA must be used within 14 days or discarded.
- Do not shake, freeze or expose to heat.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer

required. These measures will help to protect the environment.

Product Description

- What it looks like

FASENRA is a solution which is colourless to yellow. It may contain white particles.

FASENRA is available in a pack containing 1 pre-filled pen.

- Ingredients

- Active Ingredient
Benralizumab

- Inactive Ingredients

L-histidine
L-histidine hydrochloride monohydrate
 α, α -trehalose dihydrate
Polysorbate 20
Water for Injection

- MAL number

MAL21116004ACRZ

Manufacturer

Catalent Indiana, LLC
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Product Registration Holder

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Date of RIMUP revision

11/06/2025
VV-RIM-01442002
(Based on PI: VV-RIM-01442024)

Serial number

NPRA(R3/01)30012024/0291